JUL 27 2004

SECTION 2 – 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Device Information:

Category	Comments
Sponsor:	Estech 4135 Blackhawk Plaza Circle. Suite 150 Danville, CA 94506 Tel: 925-648-3500
Correspondent:	Art Bertolero Chief Executive Officer Estech 4135 Blackhawk Plaza Circle. Suite 150 Danville, CA 94506
Contact Information:	Tel: 925-648-3500 Fax: 925-648-3507
Device Common Name:	Electrosurgical Probe
Device Proprietary Name:	Cobra Adhere Surgical System
Device Classification:	21 CFR 878.4400

Predicate Device Information:

Predicate Device:	Cobra Adhere Surgical System
Predicate Device Manufacturer:	Boston Scientific Corporation
Predicate Device Common Name:	Electrosurgical Probe
Predicate Device Classification:	21 CFR 878.4400
Predicate Device Classification Number:	Class II

b. Date Summary Prepared
July 7, 2004

c. Description of Device
The Cobra Adhere Surgical System is an Electrosurgical Probe, with either a malleable or flexible shaft, used in conjunction with the Cobra Electrosurgical Unit (ESU). The System is intended for use by surgeons for the coagulation of cardiac and soft tissues during open surgical procedures.

d. Intended Use
The intended use for the Cobra Adhere Surgical System is as follows:
The Estech Cobra Adhere Surgical System is intended for the coagulation of cardiac tissue using radiofrequency (RF) energy during cardiac surgery. The System can be used during general surgery to coagulate soft tissues. The System may also be used to coagulate blood and soft tissue to produce hemostasis.

e. Comparison to Predicate Device

The Estech Cobra Adhere Surgical System is identical in nearly every way to the Boston Scientific Cobra Adhere Surgical System. The only difference between the two systems is the labeling changes necessary to list a different final manufacturer.

Both devices are manufactured by Boston Scientific on the same assembly line in San Jose of the exact same materials, processes and specifications. Both are EtO sterilized in processes validated to ISO 11135. Both devices have identical indications for use.

f. Summary of Supporting Data

No data supporting equivalence between the Estech Cobra Adhere Surgical System and the Boston Scientific Cobra Adhere Surgical System is necessary because both are the same device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 27 2004

Estech, Inc.
c/o Mr. Craig Coombs
Coombs Consulting
2029Alameda Avenue
Alameda, California 94501

Re: K041599
Trade/Device Name: Estech Cobra Adhere Surgical System™
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: June 7, 2004
Received: June 21, 2004

Dear Mr. Coombs:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041599

Device Name: Estech Cobra Adhere Surgical System™

Indications For Use:

The Estech Cobra Adhere Surgical System is intended for the coagulation of cardiac tissue using radiofrequency (RF) energy during cardiac surgery. The System can be used during general surgery to coagulate soft tissues. The System may also be used to coagulate blood and soft tissue to produce hemostasis.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041599